



# The New International Trade Architecture and Food Regulation

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# Introduction

The globalization of trade in food has brought great economic benefits. Imports have expanded consumer choices and helped maintain a competitive domestic food market. Greater competition, in turn, has resulted in higher efficiency and lower-cost food products. Food exports have generated jobs and contributed to the health of the American economy. While conferring tangible economic benefits on the American public, the expansion of international commerce also has posed considerable challenges for the U.S. food safety regulatory structure. In light of the expansion of global trade, the U.S. regulatory system has been faced with the dual challenge of protecting public health by maintaining high national food quality and safety standards, while at the same time meeting U.S. obligations under international trade treaties.<sup>1</sup>

The U.S. food safety system—comprised of several regulatory agencies promulgating and enforcing food quality and safety standards—is one of the strongest in the world. Stringent food safety regulations have a twofold advantage: they ensure high public health protection in the domestic market, and make U.S. food exports appealing to consumers abroad. Given the advantages of high food safety standards, it is essential to maintain them despite any downward pressures by the international commerce.<sup>2</sup>

This paper analyzes the implications of the new global trade architecture—with its outright prohibition of the use of food safety standards as disguised barriers to trade and its prominent emphasis on international regulatory harmonization—for the international and U.S. food safety regulation. How, if at all, will the international trade regulatory framework—comprised of the World Trade Organization (WTO) and the

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<sup>1</sup>Michael R. Taylor, *Preparing America's Safety System for the Twenty-First Century—Who is Responsible for What When it Comes to Meeting the Food Safety Challenges of the Consumer-Driven Global Economy*, 52 FOOD & DRUG L.J.13, \*26 (1997).

<sup>2</sup>*Id.*

Codex Alimentarius Commission—affect U.S food safety standards? How should the U.S. regulatory structure respond to globalization of trade in food? Should it lower its food safety standards in response to international competitive trade pressures or instead raise the global regulatory bar by exercising its global leadership? What impact will global regulatory harmonization have on national food safety regulations? Is it likely to bring national food safety requirements to a consistently high level of consumer protection—or drive them downward, thereby imperiling consumer wellbeing? What limits do cultural variables impose on global efforts at regulatory harmonization? How should governments, in promoting free trade, strike the right balance between the pursuit of economic benefits and protection of consumer health?

In analyzing the likely impact of the global trade regime on food safety, this study proceeds in the following way. Part I examines the Codex Alimentarius Commission’s newly elevated status as the WTO designated key reference authority in trade disputes. Part II considers the Beef Hormone dispute between the European Union (EU) and the United States, as the first instance of the WTO invocation of Codex standards as a reference in evaluating national food safety measures. Part III examines Codex’s structure and standard-setting process. Part IV compares Codex’s and FDA’s food safety standards and makes policy recommendations with regard to the FDA’s review of Codex standards. Part V investigates the role of culture in food regulation and its impact on harmonization. Finally, Part VI offers concluding remarks about the implications of the new global trade regime for food safety and suggests possible governmental responses.

### *I. Newly Elevated Status of Codex Alimentarius Commission*

Recognizing the desirability of harmonization of international food regulations to ease the flow of food products across borders, the United States, along with 164 other states, is a member of the Codex Alimentarius Commission—a subsidiary of the United Nations’ World Health Organization (WHO) and Food and Agri-

culture Organization (FAO)—created in 1962 with the purpose of developing and promoting an international set of food safety standards to protect consumer health and ensure fair trade practices.<sup>3</sup>

Since 1962, Codex has promulgated numerous standards, guidelines, codes of practice, and recommendations, including food commodity standards, and regular subject food standards. In the course of its standard-setting tenure, Codex has assessed the safety of over 500 food additives and contaminants and set maximum residue limits for nearly 2,500 pesticide/commodity combinations. Codex also has passed maximum residue limits for 15 veterinary drugs.<sup>4</sup>

The United States participates in Codex standard-setting process through U.S. Codex—comprised of Federal Government officials representing several Federal agencies,<sup>5</sup> including FDA, and assisted by representatives of food industry and consumer nongovernmental organizations. FDA, by participating on most Codex committees, offers scientific and regulatory expertise and conveys its views on issues concerning Codex's standards.<sup>6</sup>

At its inception, Codex's standards were aimed at facilitating trade negotiations and serving as a minimum floor of acceptable food quality and safety in less developed countries. With the enactment of recent free trade agreements, however, the status of Codex international food safety standards has been elevated, as these agreements call for member states to use Codex standards as key references in setting their own national food safety regulations. Two such agreements are the WTO accords that emerged from multilateral negotiations during the 1994 Uruguay Round Agreement on Tariffs and Trade and became effective on January 1, 1995: the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement

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<sup>3</sup>Charles Riemenschneider, *A Meeting of the Codex Alimentarius Commission*, 5 FDLI UPDATE 3 (1999).

<sup>4</sup>62 Fed. Reg. 36243 (July 7, 1997), at 36244-45.

<sup>5</sup>In the U.S. the Federal agencies that manage and carry out U.S. Codex activities include United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the Environmental Protection Agency (EPA), and the Department of Commerce (DOC). See 63 Fed. Reg. 7118, \*7118.

<sup>6</sup>Riemenschneider, *supra* note 3.

on Technical Barriers to Trade (TBT Agreement).<sup>7</sup> While the Codex Alimentarius Commission formulates international food safety standards as a model of food legislation to be considered by member governments in passing their respective national regulations, it stops short of requiring member states to adopt these measures or engage in regulatory harmonization. In other words, what Codex offers the international community is a set of safety standards that can be used by member countries as a blue print in adopting their own food safety regulations. Both the SPS and TBT Agreements take Codex's model legislation mandate a step further by expressly encouraging harmonization through the incorporation of international standards into member states' domestic regulatory frameworks.

The SPS Agreement governs, among other things, regulations intended to "1) protect human or animal life or health within a territory from risks arising from additives, contaminants, toxins, or diseases-causing organisms in foods, beverages, or feedstuffs, and 2) to protect human life or health within a territory from risks arising from diseases carried by animals, plants, or products thereof."<sup>8</sup> This agreement mandates that WTO member countries consider international standards, guidelines, or recommendations, when enacting their domestic SPS measures. A member country is not required to incorporate international standards, but must provide a scientific justification to pass a more stringent regulation affecting trade.<sup>9</sup>

In order not to violate the SPS Agreement, a regulation at issue must be based on sound scientific evidence and must be applied only to the extent necessary to protect human, animal, and plant life or health. Thus, the SPS Agreement while recognizing member states' legitimate interests in passing measures in the area of food safety regulation, guards against the use of such measures as protectionist devices.<sup>10</sup>

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<sup>7</sup>John S. Eldred & Shirley A. Coffield, *What Every Food Manufacturer Needs To Know: Realizing The Impact of Globalization on National Food Regulation*, 52 FOOD & DRUG L.J. 31, \*32 (1997).

<sup>8</sup>62 Fed. Reg. 36244 (July 7, 1997).

<sup>9</sup>*Id.*

<sup>10</sup>Eldred & Coffield, *supra* note 4, at 33.

It is important to note that the SPS Agreement designates the Codex as one of the key sources of recognized international food standards. Even though the SPS Agreement does not obligate member states to incorporate Codex standards into their domestic regulatory structures, it does mandate a scientific justification for the enactment of food safety regulations exceeding Codex requirements. While national regulatory measures based on Codex standards are presumed to be in compliance with the SPS Agreement, member states' regulations that exceed Codex minimum requirements can be challenged as unjustifiable restrictions on trade.<sup>11</sup>

In a case of a perceived violation of the SPS Agreement, a member country can bring a complaint before the WTO dispute resolution body to decide whether health and safety measures exceeding Codex standards can be scientifically justified or should be deemed an illegal barrier to trade. In the event of the WTO adverse ruling, a violating country must abide by the WTO decision or face trade sanctions.<sup>12</sup> Thus, the WTO dispute resolution structure puts some muscle behind Codex standards by designating them as a persuasive authority in the resolution of trade disputes.<sup>13</sup>

Similarly to the SPS Agreement, the TBT Agreement promotes harmonization by encouraging the use by member states of standards, technical regulations, and conformity assessment procedures that are based on work done by international standard-setting bodies. The TBT Agreement's primary goal is to deter national governments from using domestic technical regulations for protectionist purposes. Additionally, the TBT Agreement aims at ensuring that technical regulations—such as nutritional labeling and compositional food standards—are not more trade-restrictive than necessary to fulfill member states' legitimate technical objectives. Although, unlike the SPS Agreement, the TBT Agreement does not explicitly call on member states to refer to Codex standards in trade disputes, the WTO requires member states in effectuating the

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<sup>11</sup>Bruce A. Silverglade, *The Impact of International Trade Agreements on U.S. Food Safety and Labeling Standards*, 53 FOOD & DRUG L.J. 537 (1998).

<sup>12</sup>*Id.* at 537.

<sup>13</sup>Eldred & Coffield, *supra* note 2.

TBT Agreement's mandate to use all relevant international technical standards, which implicitly includes the Codex standards.<sup>14</sup>

To investigate practical food safety implications of Codex's newly elevated status as the international reference organization for food safety, it is essential to consider a beef hormones dispute—the first case where the WTO dispute resolution body invoked Codex standards as a key reference authority in a trade disagreement between the EU and the U.S. over hormones-treated beef.

## *II. The Beef Hormones Dispute*

The beef hormones dispute illustrates the response of the WTO to protectionism in the guise of a food safety measure based on local consumer preferences regarding acceptable food safety risks. The WTO ruling on Beef Hormones dispute—formally known as European Communities (EC) Measures Concerning Meat and Meat Products—was a landmark decision, offering the first interpretation of the SPS Agreement's central provisions and indicating how the WTO may handle similar disputes in the future.<sup>15</sup>

In this case, the United States and Canada challenged EC ban on imports of meat and meat products from cattle treated with growth hormones. Treating cattle with hormones—a common practice in the United States and Canada—is largely banned by the EC law. Relevant EC Directives prohibited the sale of domestic and imported meat treated with certain natural and synthetic growth hormones, providing exceptions for hormones administered by a veterinarian for certain therapeutic or zoo-technical purposes, and for certain natural hormones permitted by the EC member states regulations.<sup>16</sup>

The Codex Alimentarius—which the SPS Agreement identifies as the international standard-setting authority for veterinary residues—recommends that ingestion of hormones in accordance with good animal husbandry

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<sup>14</sup>*Id.* at 33.

<sup>15</sup>Warren H. Maruyama, *A New Pillar of the WTO: Sound Science*, 32 INT'L LAW 651, \*667 (1998).

<sup>16</sup>*Id.*

practice is “unlikely to pose a hazard to human health.”<sup>17</sup> Under the SPS Agreement, to adopt a more stringent regulation—exceeding Codex’s recommended level of protection—a country would have to provide a scientifically based justification. The WTO Panel found the EC Directives banning meat from hormones-treated cattle did not comply with the SPS Agreement’s Article 5 requirement that food safety measures be based on a risk assessment, because there was not sufficient evidence that the EC actually took into account a risk assessment when it enacted its sanitary measure.<sup>18</sup>

On appeal, the WTO Appellate Body concluded that since the EC Directive measure was more stringent than the relevant international standard it was subject to Article 3.3 of the SPS Agreement. Under Article 3.3, a member state seeking a more stringent level of protection than an international standard has to comply with the procedural requirements of Article 5.1. interpreting “risk assessment.” The Appellate Body concluded that Article 5.1, read in conjunction with Article 2.2, requires a risk assessment to be “based on scientific principles” and “scientific evidence.” Significantly, the Appellate Body construed Article 5.1 to mandate an objective relationship between the safety measure at issue and the risk assessment:

We believe that Article 5.1, when contextually read as it should be, in conjunction with and as informed by Article 2.2 of the SPS Agreement, requires that the results of the risk assessment must sufficiently warrant—that is to say, reasonably support—the SPS measure at stake.<sup>19</sup>

To put it differently, what the Appellate Body held was that an SPS measure in question is not based on “sufficient scientific evidence” for purposes of Article 2.2 and 5.1, unless it bears a rational relationship to the scientific risk assessment.

The Appellate Body agreed with the earlier panel’s ruling that given the scientific evidence showing that

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<sup>17</sup>EC Measures Concerning Meat and Meat Products—Report of the Panel, WT/DS26/R/USA. Para.8.86 (Aug. 18, 1997) at <<http://www.wto.org>>

<sup>18</sup>Steve Charnovitz, *The World Trade Organization, Meat Hormones, and Food Safety*, 14 INT’L TRADE REP.1781, \*1783 (Oct. 15, 1997).



hormones were not likely to imperil human health, the EC could not adopt a policy of “zero risk.” Specifically, the Appellate Body found that the EC had violated Articles 5.1 and 5.2, because it failed to provide a risk assessment reasonably supporting EC import ban:

In the absence of any other relevant documentation, we find that the European Communities did not actually proceed to an assessment, within the meaning of Articles 5.1 and 5.2, of the risks arising from the failure of observance of good veterinary practice combined with problems of control of the use of hormones for growth promotion purposes. The absence of such a risk assessment, when considered in conjunction with the conclusion actually reached by most, if not all, of the scientific studies relating to the other aspects of risk noted earlier, leads us to the conclusion that no risk assessment that reasonably supports or warrants the import prohibition embodied in the EC Directives was furnished to the Panel.<sup>20</sup>

Importantly, the Appellate Body held that a risk assessment should not be construed as strictly limited to quantifiable risk, thereby allowing some room for considering non-science factors that are not readily amenable to strictly quantitative analysis. However, such construction could prove dangerous if it were interpreted in the future WTO rulings as allowing risk assessment based on mere consumer preferences, public passions, or scientifically unjustified fears, such as mistrust of genetically modified foods. This potential danger of an overly-broad interpretation of the Appellate Body’s allowance for consideration of non-quantifiable factors in risk analysis should be kept in check by the overarching rule—that there must be an objective relationship between the scientific risk assessment and an SPS regulation.<sup>21</sup>

The beef hormones dispute illustrates how coordination with Codex has strengthened the WTO dispute resolution structure by infusing it with crucial scientific expertise and linking WTO standards to a multi-lateral scientific consensus. While in this dispute the EC’s import ban on hormones treated beef was ruled to violate the SPS Agreement, the decision did not foreclose the possibility of future valid food safety regulations reflecting a regionally or nationally determined “appropriate level of protection.”<sup>22</sup> What does the

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<sup>21</sup>Maruyama, *supra* note 14, at 672.

<sup>22</sup>Marsha A.Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, \*542 (1998).

status of Codex standards—as central reference authority in resolution of international trade disputes—mean for national food regulations of member states in general and for the United States in particular? Are national governments likely to feel pressured to lower their national regulations that exceed Codex standards to avoid the possibility of these measures being challenged as trade barriers? Codex standards’ presumption of validity in WTO trade disputes, raises a danger that U.S. food safety will be compromised as a result of the regulatory establishment’s effort to appease domestic food producers and food exporters that could be harmed by potential trade disputes and retaliatory trade measures from abroad.<sup>23</sup>

The concern is that the U.S. domestic regulatory bodies in deference to the interests of U.S. agricultural exporters—who do not want to be subjected to retaliatory trade measures from abroad—might allow imports of food products that are currently banned due to their failure to meet FDA food safety regulations. Domestic food producers may respond by lobbying regulatory agencies to lower food safety requirements to the level allowed for imports, so as not to be discriminated against by such a dual regulatory system, thereby lowering an overall level of consumer protection.<sup>24</sup>

Will the FDA—whose food safety requirements tend to exceed those set by Codex—feel compelled to lower its regulatory bar to accommodate food producers’ and food exporters’ interests? How should FDA structure its policy to successfully implement its public health mandate while at the same time accommodating U.S. trade interests? To examine these issues, it is first necessary to take a closer look at Codex’s standard-setting process and to compare its food safety requirements with those of the FDA.

### *III. Codex’s Standard-Setting Process and Food Safety Requirements*

Codex Alimentarius Commission’s mandate includes two competing objectives: ensuring fair international

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<sup>23</sup>Bartlett Miller, *The Effect of the GATT and the NAFTA on Pesticide Regulation: A Hard Look at Harmonization*, 6 COLO. J. INT’L ENVTL. L. & POL’Y 201, \*216 (1990).

<sup>24</sup>Silverglade, *supra* note 4, at 3.

trade in food and protecting the health of consumers. The duality of Codex's mandate sharply differentiates it from FDA, whose sole overarching mandate is to protect public health.<sup>25</sup> Due to the inherent tension between its two competing objectives, Codex is arguably ill suited to effectively safeguard consumer health. Furthermore, unlike the FDA, Codex is not subject to strict procedural guidelines that ensure that public health will be sufficiently protected. For instance, in contrast to the FDA, Codex is not subject to a codified standard requiring it to apply precautionary principles or indicating precisely how Codex is to assess whether consumer health is adequately safeguarded.<sup>26</sup>

Codex's voting rules are far from conducive to the adoption of health protective food standards. Codex adopts health and safety standards by majority vote of its member states. Under Codex's voting rules, each member country can vote on each standard under consideration. Significantly, self-interested countries are not barred from voting on the passage of standards that would promote their respective economic interests at the expense of public health protection. For instance, France and other European countries that produce and export non-pasteurized milk cheeses have blocked all Codex dairy standards that would mandate pasteurization, whereas pottery-producing countries, such as Portugal and Spain have objected to high lead standards.<sup>27</sup>

Given such voting rules, it is not surprising that at the standard-setting sessions the U.S.—whose food safety standards are generally more protective of public health than those of other Codex members—is often outvoted. If member states with weaker domestic food safety regulations were to vote for more protective Codex standards, their products would be barred from international commerce. Given the accompanying incentives to protect their respective economic interests, it is not surprising that Codex's member states are likely to vote in a manner that would advance their trade interests, and ultimately set and maintain weak

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<sup>25</sup>Lucinda Sikes, *FDA's Consideration of Codex Alimentarius Standards in Light of International Trade Agreements*, 53 FOOD & DRUG L.J. 327, \*328 (1998).

<sup>26</sup>*Id.*

<sup>27</sup>*Id.*

food safety standards.<sup>28</sup>

This systemic tendency to produce food safety standards that are insufficiently protective of public health is further reinforced by the recent amendments in Codex's procedural rules. At the twenty-third session, held in summer of 1999, the Commission amended its Rules of Procedure to emphasize that every effort should be made to reach consensus when adopting or amending codex texts.<sup>29</sup> The practical implication of this procedural amendment is likely to be a further reinforcement of a downward pressure on international food safety standards. While this procedural amendment is clearly aspirational, it nevertheless might add to the members' desire to adopt standards by a wider majority margin, which, in turn, would make it more difficult for member states to reach consensus on high standards.

The pressure to keep Codex standards low is further intensified by Codex's broad-based membership. Out of the 165 member states the vast majority is comprised of the developing countries that lack economic resources to develop and enforce rigorous domestic regulatory structures. While a broad-based membership endows Codex with an air of democratic spirit, the sharp economic disparities in the abilities of developed and developing countries to enact stringent domestic food safety regulations are likely to contribute to maintaining Codex standards weak.

The Codex standard-setting process has also been criticized for being insufficiently open and participatory. While non-governmental organizations are formally allowed to attend the Commission's meetings, their effective participation is hamstrung by the fact that they are rarely provided ahead of meetings with relevant background documents and by the fact that Codex' procedural rules preclude full dissemination of consumer views to Commission's participants. The lack of openness in Codex's standard-setting procedures can be further underscored by the Commission's adoption of certain standards in closed sessions. For instance, the Codex decision on maximum residue limits for growth-promoting hormones in meat production was passed

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<sup>28</sup> *Id.* at 329.

<sup>29</sup> Reimenschneider, *supra* note 1.

by secret ballot at the Commission's July 1995 session, despite a great interest in this matter expressed by consumer groups in many countries.<sup>30</sup>

While in recent years the attendance of Codex standard-setting meetings by consumer and environmental groups has increased, nongovernmental representation of these organizations remains sporadic at best, and the Commission has failed to reform its decision-making process to ensure adequate public participation. In sharp contrast to the under-representation of the consumer and environmental organizations, industry groups have long been closely involved in the Codex standard-setting process. For instance, at the June 1997 Codex meeting, industry interests were well represented by several food industry heavy weights, such as Coca-Cola, Pepsi Cola, Monsanto, and Pfizer, and by such trade associations as the International Dairy Federation, the International Council of Grocery Manufacturers Associations, the International Soft Drink Council, and the International Glutamate Technical Committee.<sup>31</sup>

A stark imbalance of power in the representation between industry and consumer groups was revealed by the asymmetry of representation of nongovernmental organizations that attended the 1997 Codex meeting: of the thirty-seven participating nongovernmental groups only three represented the public interest organizations. This imbalance of power was also reflected in the composition of member-states' delegations:

Whereas many of them included industry advisors, only three—from the United States, Germany, and Norway—included consumer representatives.<sup>32</sup>

#### ***IV. Comparison of Codex's and the FDA's Standards & Suggested Policy Response***

Codex's tendency to adopt and maintain standards insufficiently protective of public health is rooted not only in its flawed standard-setting procedures, its compositional makeup, and its voting rules, but also in the

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<sup>30</sup>Sikes, *supra* note 16, at 329.

<sup>31</sup>*Id.* at 330.

<sup>32</sup>*Id.*

ambiguity of Codex's sound science principles, which were designed to safeguard public health in adopting food safety standards. To better fulfill its newly elevated status as the WTO designated international reference organization for food safety, in 1995 the Codex Alimentarius Commission passed the following prudential scientific principles in the *Codex Statements of Principles Concerning the Role of Science in Codex Decisions*:

1) The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards ensure the quality and safety of the food supply.

2)

3)

4)

These principles demonstrate that in conducting its business and adopting international standards, Codex is guided by fundamental philosophy rooted in sound science and risk assessment. However, the soundness of these overarching science-based policy guidelines should not overshadow the still remaining gaping ambiguities and loopholes in the language of these principles. For instance, "other legitimate factors relevant for the health protection of consumers" referred to in the Codex's second sound principle are left undefined, as are factors relevant for "the promotion of fair practices in food trade."<sup>34</sup> Short of subsequent definition of these terms by Codex itself, these ambiguities could only be clarified by the future rulings of WTO dispute resolution panels involving Codex's standards.

To avoid gridlock caused by different understanding of these terms by different member states in formulat-

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<sup>34</sup>Michael Wehr, *Update on Issues Before the Codex Alimentarius*, 52 FOOD & DRUG L.J. 531,\*532 (1997).

ing and adopting food safety standards, Codex would have to at least clarify—if not precisely define—these key terms. Moreover, the fourth guiding principle effectively allows a member state to opt out of a Codex regulation that it finds inconsistent with its views on considerations other than the standard’s public health merits. While such “other than public health safety” considerations have not been precisely defined they may include such factors as environmental issues, social factors, or cultural values.<sup>35</sup>

This conspicuous lack of precise definitions of the key terms in Codex’s guiding principles may well be a political compromise necessary for achieving consensus between a wide range of member countries with different economic, cultural and regulatory conditions and capabilities. While this strategic ambiguity in Codex’s guiding principles clearly would undermine its effectiveness during considerations of controversial standards, it may be a necessary price for enabling Codex to function effectively in setting standards in the areas of common interests to most of its members.

The constraining impact of divergent economic and cultural interests of different member states on Codex’s adoption of uniformly high safety standards, affording adequate protection to consumers worldwide, have been demonstrated by states’ disagreements over mandatory labeling of genetically-modified foods. Codex has had difficulty in reaching a consensus on this issue due to divergent positions held by different countries.<sup>36</sup> Many countries, and especially those of the EU, have been particularly vocal in demanding mandatory labeling of genetically engineered foods. Other states, led by the United States, have argued that genetically modified foods should be subject to mandatory labeling only if they contain allergens, their composition is altered substantially, or if they contain a new food additive.<sup>37</sup>

Significantly, in advocating the mandatory labeling of genetically altered foods, many Codex members have argued that such a safety standard was justified by the consumers right to know, thus falling within the

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<sup>35</sup> *Id.*

<sup>36</sup> *Report of the Twenty-Fifth Session of the Codex Committee on Food Labeling* app. VI, Codex Doc. ALINORM 97/22 A, as cited in Michael Wehr, *supra* note 19, at 533.

<sup>37</sup> Sara M. Dunn, *From Flav’r Sav’r To Environmental Saver? Biotechnology And The Future Of Agriculture, International Trade, And The Environment*, 9 COLO. J. INT’L ENVTL. L. & POL’Y 145,\*153 (1998).

meaning of the fair trade provisions of Codex's second sound science principle.<sup>38</sup> Upon reviewing this issue, Codex's Executive Committee stated that while it is essential in setting standards to adhere closely to the four sound scientific principles to ensure product safety, the consumer's right to know was a loosely-defined factor that needed to be defined on a case-by-case basis.<sup>39</sup> Although Codex Commission has not achieved a final decision on the issue of labeling of genetically modified foods, the controversy highlights once again the difficulty of promulgating global science-based food safety standards in the areas of food safety regulation that are hotly contested by different member states.<sup>40</sup>

The problematic nature of adopting international standards in the areas of member states' divergent regulatory interests has also been underscored by the debate between the EU and the U.S. on what constitutes an acceptable level of risk in setting safety standards for several dairy products with the raw milk ingredient. The U.S. argued for mandatory pasteurization, whereas the EU countries advocated meeting only general principles of food hygiene coupled with Hazard Analysis Critical Control Points systems and end-product testing as adequate venues for ensuring product safety.<sup>41</sup> The difficulty of adopting stringent Codex standards in the areas of member states' conflicting interests has been vividly illustrated by the Commission's passage of a number of food safety standards deemed to be inadequate by the United States. For instance, over the U.S. strenuous objections, Codex approved the following measures: 1) inspection systems administered by company employees rather than by government regulators; 2) nutrient content claims prohibited by FDA food labeling regulations; 3) mineral water standards permitting higher levels of contaminants and lower levels of minerals than those allowed by FDA; 4) production of unpasteurized dairy products. Since these standards have been passed by the Codex—and therefore carry a presumption of validity in interna-

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<sup>38</sup>Wehr, *supra* note 33, at 533.

<sup>39</sup>*Report of the Forty-Third Session of the Executive Committee of the Codex Alimentarius Commission* Sec. 27-30, Codex Doc. ALINORM 97/3, as cited in Michael Wehr, *supra* note 19, at 533.

<sup>40</sup>In position papers regarding Codex labeling standards, FDA argued that all standards should be based on sound scientific principles and technical information. See Michel A. Wittaker, *Reevaluating The Food And Drug Administrations Stand On Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, \*1231-1234 (1998).

<sup>41</sup>Wehr, *supra* note 33, at 533.



tional trade disputes—the United States might be compelled to open its domestic market to imports of these products or be faced with trade sanctions.<sup>42</sup> Opening its domestic market to food imports deemed to be unsafe by the U.S. regulators, can pose a danger of creating a dual regulatory structure with more rigid food safety standard for domestically produced foods and less stringent requirements for imported food products. As such a dual regulatory structure would place domestic producers at a disadvantage, the FDA might feel compelled to lower domestic food safety regulations to the level permitted for imports, thereby endangering consumer health.

As a result of the problems embedded in its standard-setting process—the inherently contradictory nature of its mandate, its vast membership, flawed voting procedures, and the ambiguity of its sound scientific principles—Codex has adopted food safety standards that are largely less protective of consumer health than those of the FDA.<sup>43</sup> According to a 1997 report by the Center for Science in the Public Interest, there are five regulatory areas in which Codex standards fall below U.S. domestic standards: pasteurization of dairy products, food additives, mineral content of bottled water, meat inspection, and lead contamination.<sup>44</sup> In implementing its statutory mandate of protecting public health, the FDA should not adopt those Codex’s standards that do not meet statutory requirements outlined in the Federal Food, Drug, and Cosmetic Act (FDCA). In fact, in ratifying and implementing the WTO trade agreements, Congress expressly stipulated that “nothing in this Act shall be construed...to amend or modify any law of the United States, including any law relating to...the protection of human, animal, or plant life or health.”<sup>45</sup> Accordingly, FDA’s paramount goal in considering Codex standards should be effectuating its mission of safeguarding public health. In reviewing Codex’s standards for possible incorporation into the U.S. regulatory framework, FDA

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<sup>42</sup>Silverglade, *supra* note 4, at 3.

<sup>43</sup>Sikes, *supra* note 16, at 331.

<sup>44</sup>Center For Science in the Public Interest, INTERNATIONAL HARMONIZATION OF FOOD SAFETY AND LABELING STANDARDS 10-28 (1997), as cited in Lucinda Sikes, *supra* note 16, at 331.

<sup>45</sup>Uruguay Round Agreements Act, Pub. L. No. 103-465, Sec. 102(a)(2), 108 Stat. 4809, 4815 (1994) (codified at 19 U.S.C. Sec. 3512), as cited in Lucinda Sikes, *supra* note 16, at 332.

should exercise independent judgement and should not be swayed by international pressures to adopt any given Codex standard that can compromise public health in the U.S.

In considering Codex's standard for possible adoption in the domestic regulatory framework, FDA should focus only on those standards that provide equal or greater protection than those already in place in the U.S., as well as those Codex's standards that address food safety issues previously unregulated by FDA.<sup>46</sup> If adopted in the U.S., Codex's standards would have to be regularly reviewed to ensure that they provide the acceptable level of consumer protection.

FDA expressed intention to focus its review of Codex standards primarily on post-1993, as these standards have been designed to reflect the new role of Codex as the WTO designated reference organization under the SPS and TBT Agreements, whereas pre-1993 standards were primarily intended to assist developing nations in product standardization. However, given the serious problems embedded in the Codex's standard-setting process, it would be dangerous for the FDA to assume that post-1993 standards are sure candidates for acceptance into the domestic regulatory infrastructure. Recognizing the shortcomings in Codex's standard-setting process, U.S. Codex stated in 1995 that it is unlikely that regular acceptance of Codex standards will be prudent until at least the year 2000:

Ideally, within the next five to ten years...Codex standards would be established through a more transparent and fully participatory process; based on stronger, more consistent scientific principles; and fully protective of health in all countries.<sup>47</sup>

Importantly, in its review of Codex standards, the FDA should not only determine whether Codex standards fall below domestically mandated health protection requirements, but also should affirmatively object to the adoption of such weak standards by Codex and establish the record of the U.S. delegation's rational for objecting to the proposed Codex standards. In this way, even if the U.S. ultimately does not prevail in blocking the adoption of weak Codex standards, it will accumulate a record of scientifically based reasons

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<sup>46</sup>Sikes, *supra* note 16, at 332.

why the contested Codex's standards fail to afford American consumers adequate protection. Such a record can assist in deterring potential trade complaints by U.S. trading partners challenging the FDA's more stringent food safety regulation and could provide a foundation for defense in the event that a dispute is brought before the WTO.<sup>48</sup>

### ***V. The Limits of Harmonization: Impact of Culture on Food Regulation***

Whether it comes to mandatory pasteurization of dairy products, antibacterial treatment of bottled mineral water, perceived health hazards of hormone-treated beef or genetically-engineered foods, disagreements between the EU and the U.S. over these issues raise important questions of what role do cultural variables play in conflicting food safety regulations and what limits do they place on the prospects of global regulatory harmonization.

Cultural factors and attitudes influence regulation both in the EU and the U.S. These cultural influences are especially paramount in the development of regulatory measures governing the production and marketing of foods. Both the EU and the U.S. must guard the safety of food supplied to their citizens, while at the same time accommodating substantial differences in cultural attitudes and consumers' perceptions of what constitutes a food safety risk. Given significant differences between the EU and the U.S. in cultural influences and consumers' understandings of what constitutes safe food, it is not surprising that these two powerful international commercial players have been involved in a number of disputes and are likely to wage trade battles over food safety in the future.<sup>49</sup> Despite the globalization of the food production, local influences on food and dietary preferences remain strong in Europe.<sup>50</sup> Historically, Europeans have preferred traditional food practices. European consumers and regulators alike believe that traditional practices and the foods they

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<sup>48</sup>Sikes, *supra* note 16, at 333.

<sup>49</sup>Echols, *supra* note 14, at 542.

<sup>50</sup>Louis Lorvellec, *Back To The Fields After The Storm: Agriculture In The European Union After The Uruguay Round Agreements*, 2 DRAKE J. AGRIC. L. 411, \*426 (1997).

produce are safe and—importantly for most European consumers—natural. As a result, European regulatory structure permits the production of unpasteurized milk cheeses and traditional cured meats—foods that the U.S. regulators along with most scientists deem unsafe.<sup>51</sup>

The flip side of Europeans' preference for natural foods has been their deep mistrust of new food production technologies. European consumer groups have been much more vocal in their opposition to new food production and processing technologies than their U.S. counterparts. For instance, in Europe, genetically engineered corn and soybeans set off a wave of well-publicized opposition to this new technology and demands for labeling, whereas the market share of genetically engineered crops in the U.S. continues to grow without significant opposition from consumer groups.<sup>52</sup>

In response to vociferous opposition by consumer groups, European regulatory bodies have called for mandatory labeling of genetically modified foods to inform consumers of the underlying process of food modification.<sup>53</sup> The FDA, by contrast, does not require labeling of genetically modified foods if their composition is not significantly altered and if they do not contain allergens. Since U.S. regulatory agencies, based on scientific data, have concluded that there is no substantial difference between genetically modified and traditional foods, and therefore genetically altered foods do not require special labeling—unless there are narrowly defined safety issues—the U.S. has opposed the EU's requirements of labeling of biotechnology foods as scientifically unwarranted.<sup>54</sup>

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<sup>51</sup>Echols, *supra* note 14, at 542.

<sup>52</sup>Jeffrey Kluger, *Atlantic Food Fight: The Battle Heats Up Between The U.S. and Europe Over Genetically Engineered Crops*, TIME, September 13, 1999, at 42.

<sup>53</sup>*European Union: France Issues Labeling Rules To Implement EU's Directive On Genetically Modified Food*, BNA INTERNATIONAL ENVIRONMENTAL DAILY, Feb.14, 1997, at D2 (In reaction to the European Commission's decision approving imports of genetically modified corn seed, the French government mandated stringent labeling requirements for genetically modified food.)

<sup>54</sup>Judith E. Beach, No "Killer Tomatoes": *Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L. J. 181, \*182 (1998). (Arguing that based on extensive regulatory review and testing, FDA, USDA, and EPA concluded that genetically modified plants are as safe as plants bred with traditional agricultural methods, so that, unless specific safety issues are raised, special labeling of genetically engineered foods is not required).

The United States' cultural attitudes toward food has been reflective of the Americans being more receptive of technological innovation in general and its application to agriculture and food industry in particular. Among U.S. consumers, trust in scientific method of risk assessment of any hazards associated with novel method of food production and processing, by and large, has triumphed over a deep seated suspicion of any method of food production that is not natural—i.e. not produced by traditional farming or agricultural methods.<sup>55</sup>

The disparity between the EU and U.S attitudes toward new technologies and traditional methods of food production largely stems from their vastly different agricultural traditions. In Europe, going back to the Middle Ages, the link to the land and traditional form of agriculture is strong. Raw milk cheese and traditional cured meats are favored by European consumers and are permitted by regional and national regulatory structures. Safety of these foods is assumed based on a centuries-long tradition of consumption rather than on scientific laboratory evidence.<sup>56</sup>

In the U.S., by contrast, technological innovation has played a salient role in transforming American agriculture. New technologies—and especially biotechnology—have enhanced U.S. agricultural sector's productivity and competitiveness, while improving food safety and quality. As a result of this technologically driven agricultural transformation—which brought consumers tangible and readily observable benefits—U.S. public largely embraced novel food production and processing methods, such as genetic engineering and irradiation.<sup>57</sup>

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<sup>55</sup>Echols, *supra* note 14, at 542.

<sup>56</sup>*Id.* at 528.

<sup>57</sup>*Id.* at 529.

Since 1992, when the genetically modified Flav'r Sav'r Tomato was first introduced in the U.S., American consumers have seen the emergence of a robust market for genetically engineered agricultural products—which includes corn, potatoes, soybeans, squash, carrots, papaya and other agricultural commodities.<sup>58</sup> In contrast to their European counterparts, American consumers often deem traditional methods of food production—such as those employed in production of raw milk cheeses and cured meats—as unsafe. American consumers' cultural attitudes are reflected in the U.S. regulatory scheme, which relies on a scientific method of assessing food safety and creates a regulatory structure conducive to the development of new food technologies, while demonstrating a fair amount of skepticism about the safety of some traditional food production methods.<sup>59</sup> While the influence of culture on food safety regulations looms large in the EU and the U.S., it is restricted by their respective national laws, as well as by their membership in the WTO. The SPS Agreement, in particular, limits the ability of national regulatory structures to enforce parochial cultural attitudes about food safety by encouraging member states to rely on a standardized, global, science-based approach to regulation. However, given the long history of different cultural attitudes to food—as has been illustrated by EU-U.S. divide on a number of issues—how likely is it that a new global trade and regulatory infrastructure will overcome these long-standing cultural differences. Can international harmonization mitigate, if not eliminate, these culturally rooted regulatory divides?

## ***VI. Conclusion: Global Attempts at Strengthening Food Regulation***

Partly as a response to the heightened focus on food safety regulations as potential barriers to trade—as reflected by controversies between the EU and the U.S. over the hormones-treated beef and genetically engineered foods—the international community has responded with a proposal to undertake the formation of an international food agency. For instance, director of the WHO has expressed an intention to create a

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<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 530.

global food agency as part of the UN.<sup>60</sup> The attempts to strengthen food regulation on a global level can also be seen in the efforts by Organization for Economic Cooperation and Development (OECD) member states to establish new, stronger national food regulation agencies in the OECD member states.<sup>61</sup>

These efforts are likely to be expedited by the rising tide of international commerce, raising concern of a downward regulatory spiral. The danger is that without coordinated global regulatory cooperation, states—in the pursuit of economic gains from trade—will engage in the regulatory race to the bottom. To ensure that national food regulations afford consumers an adequate level of protection, many governments strive to heighten their national regulatory structures, while coordinating these efforts with their counterparts abroad. Given the cultural, political, and economic constraints on international regulatory harmonization, the most promising strategy of strengthening food safety regulation globally would be to strengthen food safety regulation by individual countries at the national level and use international institutions such as Codex to coordinate these efforts at the international level.

Through its participation in Codex and other multilateral organizations, the U.S. should assume a leadership role to ensure that international regulatory harmonization assumes an upward rather than downward trajectory. With regard to the incorporation of Codex's standards into the U.S. domestic regulatory structure, the FDA should adopt Codex standards only if they will improve food safety and only if they will provide adequate protection to American consumers.

In light of its limited resources, the FDA should focus on considering incorporating Codex standards that afford a higher level of protection than existing FDA standards or govern food safety issues not yet regulated by the FDA. In implementing the review and the adoption of the Codex standards, FDA should adhere to the democratic principles of openness and public participation, providing ample opportunities for the public

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<sup>60</sup>Myron S. Weinberg, *Global Corner*, 5 FDLI UPDATE 7 (1999).

<sup>61</sup>*Id.*

to comment on the Codex standards being considered for adoption in the U.S.<sup>62</sup>

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<sup>62</sup>Sikes, *supra* note 16, at 335.